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April 20, 2021

VIA ELECTRONIC FILING

Hon. Christian F. Hummel
United States District Court
Northern District of New York
445 Broadway, Room 441
Albany, NY 12207

Re: *Novartis Pharma AG et al v. Regeneron Pharmaceuticals, Inc., 1:20-cv-00690-TJM-CFH*

Dear Judge Hummel:

We, along with Goodwin Procter LLP, are counsel to Plaintiffs Novartis Pharma AG, Novartis Pharmaceuticals Corporation and Novartis Technology LLC (together, "Novartis") in the above-referenced action (the "NDNY action"). I write in response to the letter filed by defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") on April 16, 2021. As discussed in more detail below, contrary to Regeneron's suggestions, there is nothing exceptional requiring the stay to remain in effect and the case is in a position to move quickly towards trial. Accordingly, Novartis maintains its request that the Court schedule a Rule 16 conference at its earliest convenience.

A. The Stay Under 28 U.S.C. §1659 Should Be Lifted

Regeneron's only argument as to why the stay under 28 U.S.C. § 1659 should not be lifted now is that it would be "premature" to do so because, although the ITC Administrative Law Judge ("ALJ") has issued an initial determination terminating the Investigation, the Commission is not required to issue its final determination until May 8, 2021. Tellingly, neither Regeneron nor the Staff attorney opposed Novartis' motion to terminate, and Regeneron does not argue that the Commission will do anything other than affirm the ALJ's initial determination.

Moreover, this case was stayed under 28 U.S.C. § 1659 only at *Regeneron's* request based on the pendency of the ITC action (as was permitted by statute). The ITC action is now over for all intents and purposes, with only the ministerial act of the Commission approving the ALJ's Initial Determination remaining. As Regeneron acknowledges, that

ministerial act will occur no later than May 8. There is no reason for Regeneron to continue to resist moving this case forward.

However, to the extent that Regeneron insists on making the Court and Novartis wait to lift the stay until May 8 — when Regeneron acknowledges the stay must by statute be lifted — Novartis submits that the Court should schedule a Rule 16 conference for the earliest date it is available following May 8.

B. <u>The Case Should Not be Stayed on the Basis of Regeneron's Newly-Filed IPR</u>

Regeneron acknowledges that a stay pending IPR proceedings is generally not granted unless and until the PTAB actually institutes the IPR. *See, e.g., Rensselaer Polytechnic Institute v. Apple Inc.*, No. 1:13-cv-0633 (DEP), 2014 WL 201965 (N.D.N.Y. Jan. 15, 2014); *PPC Broadband, Inc. v. Corning Gilbert, Inc.*, No. 5:12-cv-00911 (DEP) (N.D.N.Y. July 16, 2013). It argues, however, that the "unique history" of this case warrants a deviation from the accepted practice. Novartis submits that, on the contrary, the history of this case, including its advanced state based on the work already done in the ITC Investigation, strongly supports the denial of a stay.

The weakness in Regeneron's position is evident from the fact that it bases its argument almost entirely on the pretrial brief submitted by the Staff attorney in the ITC Investigation. What Regeneron neglects to inform the Court is that the Staff attorney was simply a party to the ITC Investigation, the same as Novartis and Regeneron. Accordingly, the Staff attorney's pretrial brief was just that, a brief, and the ALJ was under no obligation to accept his positions on validity (many of which supported Novartis) any more than he would be obliged to accept the positions advanced by Regeneron in its prehearing brief. Indeed, the ALJ had already rejected some of the Staff attorney's positions on indefiniteness in the context of claim construction. Moreover, the prehearing briefs were filed before the parties' evidentiary showings at the final hearing, and the Staff attorney himself would have been free to change his positions on validity based on the evidence.

Contrary to Regeneron's unsupported speculations, the Staff attorney's positions on validity were not the reason for Novartis's decision to terminate the ITC Investigation, and should likewise have no bearing on the PTAB's decision as to whether to institute an IPR. As Regeneron knows, Novartis made clear in its motion to terminate (attached as Ex. 1) that it "strongly believe[d] it would prevail on the merits in this investigation—indeed, the Administrative Law Judge recently granted Novartis's motion for partial summary determination that Regeneron directly infringed [the '631 patent]—[and] that the ['631 patent] is valid and that Regeneron cannot prove otherwise." Novartis's reason for terminating the Investigation had to do with the potential remedy available at the ITC; the Staff attorney advocated that, based on the public interest, "the Commission should delay the implementation of [any exclusion order] by at least three years." Accordingly, Novartis decided to "pursue relief in district court."

Regeneron's contention that there would be no prejudice to Novartis should the case be stayed because Novartis's decision to terminate the ITC case demonstrates a "lack of urgency" is likewise demonstrably incorrect. On the very day that Novartis moved to terminate the ITC Investigation, it sent a letter to this Court (Dkt. # 31) asking for the stay to be lifted and for the case to proceed expeditiously to trial based on the work done in the ITC Investigation.

In short, Regeneron's assertion that "the likelihood of institution is high" is nothing more than unsupported attorney argument, and the Court should not, in contravention of regular practice, entertain a stay on that basis.

C. <u>The Case Can Move Quickly to Trial</u>

Regeneron does not dispute that the ITC Investigation was trial-ready or that almost all the issues in this case were also at issue in the Investigation—including infringement and validity under 35 U.S.C §§ 102, 103, and 112. The parties engaged in extensive fact and expert discovery, including almost 6 million pages of documents produced, 18 fact depositions, 58 interrogatories and responses (including detailed contention interrogatories), 20 expert reports, and 13 expert depositions. The fact discovery from the ITC Investigation can be cross-designated and used in this case (as it has been in the SDNY case), and any additional fact discovery on these issues should therefore be minimal. Accordingly, Regeneron's assertion in its letter that "discovery in this case has not even started" is, at best, disingenuous. Similarly, based on the contentions and expert reports served in the ITC Investigation, it should take little time for the parties to prepare contentions and expert reports here. Significantly, under 28 U.S.C. § 1659(b), the record from the ITC Investigation "shall be transmitted to the district court and shall be admissible in the civil action, subject to such protective order as the district court determines necessary, to the extent permitted under the Federal Rules of Evidence and the Federal Rules of Civil Procedure." The purpose of this statute is to expedite the district court proceedings. *See* H.R. Rep. No. 103-826(I) at 142 (1994) (legislative history of § 1659) ("[U]se of the Commission record could expedite proceedings and provide useful information to the court.").

The only issue that Regeneron identifies in its letter that was not fully addressed in the ITC Investigation is its forthcoming counterclaim alleging unenforceability due to purported inequitable conduct—a defense Regeneron could have raised in the ITC but did not. But even on that issue, discovery would not be starting fresh in this case. Discovery on inequitable conduct is already proceeding apace in the SDNY action, as inequitable conduct is a predicate for Regeneron's antitrust claim (which is exactly why the antitrust case is a compulsory counterclaim to Novartis's infringement claims here and should not have been separately brought in SDNY). Similar to the discovery from the ITC Investigation, the inequitable conduct discovery from the SDNY case can be cross-

designated and used here, requiring little if any further discovery on the issue. Significantly, the principal party from which Regeneron claims it will need third-party discovery in this case—Vetter—is a party to the SDNY action. Cross-designation of SDNY discovery should therefore completely dispose of Regeneron's concern about needing to proceed under the Hague convention.

Unlike in the ITC, Novartis seeks damages in this action. But due to the advanced stage of the liability case, Novartis will propose bifurcating damages discovery and trial. Even if the issue of damages is not bifurcated, given that it is the only issue for which discovery has not yet taken place, the parties should be able to complete discovery expeditiously.

In sum, although Regeneron's letter includes a lengthy table intended to show that there is much left to do in this case, as set forth below, the truth is that the lion's share of the work listed in the table, including discovery (both fact and expert), contentions, and claim construction, has already been completed in the ITC Investigation or is already underway in the SDNY case:

- **Pleadings**: Regeneron will need to respond to the complaint promptly once the stay is lifted, and the case can move forward regardless of whether Regeneron decides to make a partial motion to dismiss.[1] Although Regeneron states in its letter that "it will not be required to answer the complaint until after the Court resolves" its potential motion to dismiss here, Regeneron has pressed for discovery to go forward in its SDNY case, even though Novartis has a motion to dismiss pending there.

- **Local Patent Rules**: As noted above, exchange of contentions and claim construction already took place at the ITC. Regeneron's inclusion in its table of "Disclosure of Novartis's infringement contentions" exemplifies the problem with its position, as Regeneron conceded infringement in the ITC Investigation and the ALJ granted the ITC equivalent of summary judgment of infringement.

[1] Regeneron provides two bases for its proposed motion to dismiss, but neither has any merit. With respect to willfulness, Regeneron is an admitted infringer and its assertion that the Staff attorney's brief makes Novartis's willfulness allegations "not plausible" is misguided. As set forth above, the Staff attorney's brief was only a brief, and his position on invalidity was a result of significant (and obvious) legal and factual errors. Moreover, the Staff attorney's brief of course says nothing about what Regeneron believed at the time it made the decision to infringe the '631 patent. There is also nothing "improper" about Novartis's request for injunctive relief. Novartis made clear in its motion to terminate that it "believes that there are no public interest concerns that would [have] justif[ied] tailoring any remedy that could issue in [the] Investigation" and that it "disagree[d] with Staff" with respect to its conclusion on public interest. Significantly, Regeneron's argument at the ITC against issuance of an exclusion order was based in significant part on the COVID-19 pandemic, and there is no reason to believe the situation will be the same at the time an injunction would issue in this action.

- **Other Discovery**: As discussed, fact discovery, including third-party discovery, already took place in the ITC Investigation and is ongoing in the SDNY case. Discovery from both cases can be cross-designated here. Expert discovery likewise was already conducted in the ITC Investigation, so it will take the parties little time to complete in this case.

Tise case, therefore, is "unique," but not in the way Regeneron suggests. Although we have not yet had a Rule 16 conference, almost all of the pretrial work has already been completed and the case is in a position to be expedited for trial.

D. The Possible Transfer of the SDNY Case Should Not Impact the Schedule

As mentioned above, Regeneron's allegation of inequitable conduct is a necessary (but not sufficient) predicate to its antitrust claims. If Regeneron fails to prove inequitable conduct by clear and convincing evidence (which Novartis believes it will not be able to do), its antitrust claims must fail. Accordingly, even if Regeneron's antitrust claims are transferred from SDNY to this Court, they should be bifurcated and stayed pending a decision on inequitable conduct. Indeed, this is how courts regularly handle antitrust counterclaims in patent cases. *See, e.g., In re Innotron Diagnostics*, 800 F.2d 1077 (Fed. Cir. 1986).

* * *

For the reasons set forth above, Novartis respectfully requests that the Court lift the stay and schedule a Rule 16 conference at its earliest convenience. Any procedural issues that Regeneron wishes to raise can be resolved in the context of the Rule 16 conference and in the Civil Case Management Plan that will be submitted in advance of the conference.

Counsel is available should your Honor have any questions.

Very truly yours,

BOND, SCHOENECK & KING, PLLC

George R. McGuire
Member

GRM/

cc: Counsel of Record